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(54) A package for surgical devices

Packung für chirurgische Vorrichtungen

Emballage pour des dispositifs chirurgicaux

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to packages for surgical instruments and devices, and more particularly to moisture impervious packages for surgical devices such as suture-needle assemblies which may be packed in a conditioning fluid medium.

2. Discussion of the Prior Art

Packages constructed of moisture impervious materials for surgical instruments and elements, such as surgical suture-needles and sutures in general, are well known in the art. These packages generally include a retaining member for holding the surgical elements in place within the package. The retainer is completely enclosed and sealed within the package to maintain sterility and prevent contamination of the surgical elements.

Packages constructed of moisture impervious material for surgical elements such as sutures and suture-needle assemblies are generally sealed by means of a heat seal device which creates a peripheral heat seal about the outer edges of the package. The material of which these packages are constructed usually include metal foil such as aluminum backed in laminate form with a plastic material such that the plastic forms the interior surface of the package.

The package is generally formed from a first wall of material upon which the retaining device holding the sutures or suture-needle assemblies is placed. A second wall then overlays the retainer and first wall of material, and a weld seal is formed by applying heat and pressure about the peripheral edge to completely seal the package and form the pocket therebetween which houses the retainer and sutures. This construction however, makes opening the package difficult and handling of the sutures inconvenient since the package typically must be torn open to access the contents.

In an improved form of package the second wall may cover only a portion of the retainer and first wall, and a closure flap member is then positioned to cover the remainder of the retaining device and first wall, and to overlap the second wall. The flat heat seal is then formed about the periphery of the package to seal the first wall to the second wall and the closure flap, as well as to seal the closure flap to the second wall to completely seal the package. In this construction an adhesive layer is provided between the closure flap and the first and second walls so that the package may be peeled open without tearing, by pulling the closure flap. This "mid-peel" construction facilitates opening of the package and makes handling of the sutures easier.

Many sutures and suture-needle assemblies require moisture impervious packaging to prevent evaporation of the conditioning fluid medium in which these elements are packaged. For example, sutures constructed of a gut-type material or a collagen material typically are packaged in a conditioning medium such as alcohol to prevent the sutures from drying out and cracking. In order to eliminate the possibility of evaporation of the alcohol medium, moisture impervious packages are provided to seal the alcohol therein and prevent leakage. To this end, the heat seal which is formed about the periphery of the package must also be impervious to moisture and not be susceptible to cracking in order to prevent the leakage and evaporation of the alcohol medium.

The mid-peel package with the peelable closure flap provides distinct advantages over the conventional tearable foil packages and is preferred. Depending on how the manufacturing and assembly process is conducted, however, it has been found that the presence of an alcohol conditioning fluid may cause difficulties in assembling the package so that the package seal is not compromised. By way of example, if the conditioning fluid is added before the closure flap is sealed to either or both of the first or second walls it is possible that alcohol vapor from the conditioning fluid may interfere with or hinder the adhesive curing process. This may cause an inadequate seal, possibly due to microscopic cracks or fissures across the seal area, thereby allowing the alcohol conditioning fluid to leak or evaporate from the package over time, resulting in a stiff suture at the time of use.

An "end-peel" package is known from, for example, DE-C1-4020089 which discloses a package formed of a bottom wall, a top wall and a layer which covers the entirety of the top wall. These elements are joined by a peripheral seal, with the exception of a portion adjacent to one of the edges.

A mid-peel package is known from EP-A1-0 471 441 which discloses a package system for synthetic absorbable surgical elements. Part of the system is a pouch formed of a bottom wall and a divided top wall. Part of the top wall is provided with a gripping portion and can be peeled off the bottom wall in order to expose the contents of the pouch.

The novel packaging device for surgical elements such as sutures and suture-needle assemblies of the present invention obviates the disadvantages encountered in the prior art tearable packages and provides an improved peelable package which substantially eliminates the possibility of leakage of a conditioning fluid medium through the peripheral seal about the edges of the package. Sutures and suture-needle assemblies packaged in the conditioning medium are preserved in the package of the present invention through the provision of a novel arrangement to prevent the leakage and evaporation of the conditioning fluid from the moisture impervious package.

The present invention provides a novel package for

a surgical instrument or element in accordance with claim 1 and a method for packaging a surgical suture retainer in accordance with claim 9.

The package is constructed of a moisture impervious material and substantially reduces or eliminates the possibility of leakage of a conditioning fluid medium enclosed in the package through cracks in the peripheral heat seal or separations between the layers which may provide a path from the interior of the package to the external environment.

The package of the present invention provides a bottom wall of moisture impervious material which overlies a top wall of moisture impervious material having substantially the same dimensions as the bottom wall to form a pocket therebetween and further includes a closure flap positioned on the top wall to facilitate opening the package and includes means for accessing the device enclosed therein. The top wall is secured to the bottom wall by a substantially moisture impervious peripheral seal. The closure flap is secured to the top wall by a substantially moisture impervious peelable peripheral seal. A surgical instrument or element, in particular sutures or suture-needle assemblies which may or may not be assembled on a retainer device, are positioned in the pocket between the two walls of material. The closure flap overlies less than the entirety of the top wall and the peelable seal which secures the closure flap to the top wall includes a portion which extends across the package, and the peripheral seal between the top and bottom walls is non-peelable. Advantageous embodiments of the inventive package and method are defined in the dependent claims.

In one of these embodiments, the top wall is provided with a die-cut region which may include a series of perforations, a tearable score line, or cut in the material, each of which is preferably in the shape of a "U" to form a tab which is drawn back away from the top wall to access the retainer. In this embodiment, the closure flap includes an additional seal which seals the tab to the closure flap, so that upon removal of the closure flap, the tab is pulled away from the top wall. The package is formed by placing the retainer on the bottom wall heat sealing the closure flap to the top wall about its periphery and across its middle to seal the flap to the tab, and then heat sealing the top wall to the bottom wall about its periphery to enclose the retainer therein.

Many types of sutures, such as gut-type sutures or collagen-type sutures require packaging in a conditioning fluid medium such as alcohol to preserve their suppleness and flexibility. After the sutures and conditioning fluid are positioned between the two walls of material, a peripheral heat seal is applied about the longitudinal edges and the top and bottom transverse edges to form a continuous seal about the package. The heat sealing process tends to accelerate the vaporization of the alcohol, so solidification of the bond between the layers is critical. The seal, being only between the substantially identically dimensioned bottom and top walls, substantially reduces or prevents evaporation at the heat seal. The provision of the bottom and top walls having the same shape and dimensions substantially eliminates the possibility of microscopic leaks and cracks forming in the heat seal at the juncture of the closure flap and the top wall to prevent the leakage or evaporation of the conditioning fluid from the interior of the package to the outside environment. Because the bottom and top walls are not to be peeled apart, the peripheral seal between the bottom and top walls need not include an adhesive to permit peeling. Rather, the peripheral seal between the bottom and top walls can be a traditional heat weld seal wherein the polymer inner layer of each wall partially melts and flows together to become a unitary layer. In such a weld seal the polymer layer solidifies as a unitary layer relatively quickly. Peelable bonds including an adhesive layer, on the other hand, require a longer set up time during which vapors from the conditioning fluid can interfere with formation of an effective sealing bond.

The package of the present invention having the closure flap over the window access area possesses several advantages over known packages, particularly during opening of the package. The removal of the closure flap provides access to the suture needles through a one-step opening motion, giving access to the needles without having to regrasp and reposition the package after opening. Less effort is expended during opening, and there is less chance of mishandling the package and sterile suture-needles contained therein during opening. Furthermore, the retainer may be constructed to have a fold-over panel adjacent the needles which is adhesively bonded to the closure flap, or to the die-cut flap, so that opening the closure flap lifts the retainer and exposes the needles while securing the closure flap to the package. In an alternative embodiment, the die cut tab provides added protection to the cover flap in the event the needles shift, in order to prevent puncturing the cover flap. Most importantly, in the present invention the closure flap may be adhered to the top wall before the bottom and top walls are adhered to one another to form the pocket to receive the surgical suture and conditioning fluid. Thus, the closure flap may first be bonded to the top wall with an adhesive layer therebetween so as to form a peelable seal between the closure flap and top wall. Thereafter, the bottom and top walls are welded together to form the pocket to receive the suture and conditioning fluid. Because the peelable closure flap is applied to the top wall before the bottom and top walls are bonded together, and because the bottom and top walls are weld sealed together without any adhesive layer, the bottom and top walls may be welded together to form the pocket on line at the same time the suture and conditioning fluid are added to the pocket. In this manner a peelable package is provided while advantageously permitting on line formation and loading of the package.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features of the present invention will become more readily apparent and may be understood by referring to the following detailed description of an illustrative embodiment of the package for a surgical suture retainer, taken in conjunction with the accompanying drawings, in which:

Figure 1 illustrates an exploded perspective view of a first embodiment of the package of the present invention;
Figure 2 illustrates a plan view of the package of Figure 1;
Figure 3 illustrates a perspective view of the package of Figure 1;
Figure 4 illustrates a perspective view of the package of Figure 1 in the opened condition;
Figure 5 illustrates an exploded perspective view of a second embodiment of the package of the present invention;
Figure 6 illustrates an exploded perspective view of a third embodiment of the package of the present invention;
Figure 7 illustrates a plan view of the package of Figure 5;
Figure 8 illustrates a perspective view of the package of Figure 5;
Figure 9 illustrates a perspective view of the package of Figure 5 in the opened condition;
Figure 10 illustrates a side cross sectional view of the package of Figure 1; and
Figure 11 illustrates a side cross sectional view of the package of Figure 5.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings, in which like reference numerals identify similar or identical elements throughout the several views, Figure 1 illustrates an exploded view of the package of the present invention showing all the elements that make up package 10. Package 10 is constructed of a moisture impervious material such as metal foil such as aluminum or a combination of a metal foil and plastic laminate such as polyolefin which substantially prevents moisture from penetrating from the inside of the package to the external environment. A bottom wall 12 is provided upon which a surgical suture-needle retainer is positioned. Retainer 18 preferably contains a plurality of surgical suture-needle assemblies 20 whereby the needles 22 of the assemblies 20 are positioned at an upper edge of the retainer 18 as shown. A top wall 14 is provided to overlie bottom wall 12 having retainer 18 positioned thereon. A closure flap 16 is provided which covers access means 24, whose function will be described below. Bottom wall 12 and top wall 14 form a pocket to enclose retainer 18 therebetween.

As seen in Figures 2 and 3, closure flap 16 is secured to top wall 14 by a peelable peripheral heat seal 32 which encloses and seals access means 24. After retainer 18 is positioned on bottom wall 12, top wall 14, having closure flap 16 attached thereto, is then sealed to bottom wall 12 by peripheral heat weld seal 30. Retainer 18, having suture needles assembly 20 wound thereon, is thereby sealed within moisture impervious package 10 to prevent the evaporation of a conditioning fluid which is applied to the sutures in retainer 18. In all of the embodiments described herein, first and second walls 12, 14 preverably include aluminum foil and polymer layers, and are heat sealed together with the polymer layers in face to face relation so as to form a weld seal therebetween with the polymer layers flowing together to form a unitary layer. The closure flap also includes aluminum foil and polymer layers. In order that the seal between the closure flap and second wall is peelable, however, an adhesive heat seal coating layer is provided between the closure flap and second wall, such as by adding an adhesive heat seal coating layer to the polymer layer on the closure flap. In a preferred construction the first and second wall are a nylon foil laminate, such as $1.524 \cdot 10^{-2}$ mm (0.6 mil) nylon laminated to $5.08 \cdot 10^{-2}$ mm (2 mil) foil. It is contemplated that polyethylene or other polymers may be used instead of nylon on the first and second walls. The peelable closure flap preferably is constructed of $2.54 \cdot 10^{-2}$ mm (1 mil) foil laminated to $3.81 \cdot 10^{-2}$ mm (1.5 mil) high density polyethylene, the polyethylene being coated with RP-1A (Rollprint Packaging, Addison Illinois) heat seal coating at a coating rate of from about 0.06 Pa to about 0.12 Pa (0.02 to about 0.04 ounces per square foot).

Gut-type sutures and other degradable bioabsorbable type sutures require a conditioning fluid to be packaged with the sutures to prevent drying out or cracking. The conditioning fluid is typically an alcohol based fluid medium which maintains the suppleness and flexibility of the sutures within the package. The moisture impervious package is provided to prevent the evaporation of the conditioning fluid, and consequently the destruction of the suture material, and with such a package it is important the package be moisture impervious and that the heat seal which joins the top wall to the bottom wall maintains its integrity throughout the life of the package.

To this end, package 10 of the present invention provides for a continuous heat seal 30 about bottom wall 12 and top wall 14. Closure flap 16 is secured to the top wall 14 by peripheral seal 32 to eliminate the junction between the closure flap, the bottom wall, and the top wall. In use, top wall 14 is formed as having substantially identical dimensions to bottom wall 12, with the addition of a die cut access means 24 being provided in top wall 14. Access means 24 may comprise a window-like opening, which provides access to the retainer 18, and in particular the needles 22, packaged within pack-

age 12. Closure flap 16 is first sealed by means of peripheral heat seal 32 to top wall 14 to fully enclose access means 24. Retainer 18 is positioned on bottom wall 12 and top wall 14, having closure flap 16 sealed thereto, is then positioned on bottom wall 12 so that needles 22 lie beneath the region of access means 24. Heat seal 30 is then applied to the periphery of package 10 to enclose retainer 18 within package 10.

As best seen in Figure 4, a gripping tab 34 is provided on closure flap 16 to allow surgical personnel to grasp flap 16 to open the package 10. As closure flap 16 is pulled away from top wall 12, peelable seal 32 is broken to allow for closure flap 16 to be peeled away from top wall 14. Needles 22 of suture-needle assemblies 20 are positioned within access means 24 to allow suture-needle assemblies 20 to be readily removed from the package through access means 24. Preferably, closure flap 16 remains joined to package 10 at top edge 36.

Figures 5 and 6 show alternate embodiments of the package of the present invention which are identical to package 10 of Figure 1 except for the provision of access tab 42 instead of access means 24 of Figure 1. In Figure 5, access tab 42 is constructed by applying a U-shaped die cut 44 to top wall 14 which is peelable from top wall 14 in a manner described below. Figure 6 illustrates access tab 42 as being U-shaped through the provision of perforations 46. While both embodiments show access tab 42 to be U-shaped, it is recognized that die cut 44 or perforations 46 may be continuous so that tab 42 is a removable panel upon opening of the package. In both embodiments, it is contemplated that needles 22 of retainer 18 are positioned beneath access tab 42 so that upon opening of the package the needles are accessible by the surgical personnel.

Figures 7 and 8 illustrate package 40 which is identical to package 10 except for the further provision of a substantially transverse heat seal 48. As described above in relation to package 10, gripping tab 16 is secured to top wall 14 by peripheral heat seal 32 to fully enclose access tab 42. In this embodiment, however, substantially transverse heat seal 48 is also applied to secure closure flap 16 to top wall 14 across access tab 42 so access tab 42 is secured to closure flap 16. After retainer 18 has been positioned on bottom wall 12, top wall 14 having closure flap 16 secured thereto is positioned on bottom wall 12 so that access tab 42 overlies needles 22. A peripheral heat seal 30 is then applied in the manner described above to secure top wall 14 to bottom wall 12.

As seen in Figure 9, gripping tab 34 is grasped to pull closure flap 16 away from top wall 14. As peripheral heat seal 32 is broken, access tab 42 is turned upwardly with closure flap 16 due to transverse seal 48 so that access tab 42 is peeled away from top wall 14 to reveal retainer 18 and needles 22 beneath access tab 42. It is preferred that closure flap 16 remains attached to top wall 14 at top edge 36, while access tab 42 remains secured to top wall 14 at edge 50.

As stated above, access tab 42 may be formed by a continuous die cut 44 so that as closure flap 16 is peeled away from top wall 14 as shown in Figure 9, access tab 42 is completely removed from top wall 14. Closure flap 16 remains secured to top wall 14 at top edge 36.

A further advantage of access tab 42 over an opening such as access means 24 is that in the unlikely event that needles 22 shift in retainer 18, there is added protection against puncture by the needle tips from access tab 42, which reduces the possibility of puncture of closure flap 16.

Figures 10 and 11 illustrate side cross-sectional views of the package 10 and 40, respectively, showing the provision in Figure 10 of peripheral seal 32 and in Figure 11, showing the additional provision of transverse seal 48.

The claims which follow below define various embodiments of the invention additional to those described in detail above.

Claims

1. A package (10) for a surgical suture retainer (18) in conditioning fluid comprising:

   a wall (12) of substantially moisture impervious material forming a bottom of said package,

   a wall (14) of substantially moisture impervious material forming a top of said package, said top wall having substantially the same dimensions as said bottom wall and being positioned in overlying relation on said bottom wall to form a pocket therebetween for receiving said retainer, said top wall being secured to said bottom wall by a substantially moisture impervious peripheral seal (30), the peripheral seal (30) between the top and bottom walls being non-peelable;

   means (24, 42) for accessing said retainer through said top wall, and

   a closure flap (16) of substantially moisture impervious material overlying at least a portion of said top wall and enclosing said accessing means, said closure flap being secured to said top wall by a substantially moisture impervious peelable peripheral seal (32),

   wherein

   the closure flap (16) overlies less than the entirety of the top wall (14) and the peelable seal (32) which secures the closure flap to the top wall includes a portion which extends across the package.

2. A package according to claim 1, wherein said closure flap includes a gripping tab (34) to facilitate removal of said flap from said top wall.

3. A package according to any one of claims 1 or 2, wherein said access means comprises a cut-out region (24) in said top wall.

4. A package according to any one of the preceding claims, wherein the substantially moisture impervious peripheral seal between said bottom and top walls is a heat seal (30) and

said access means exposes a portion of said retainer (18), said access means being enclosed by and sealed by said closure flap.

5. A package according to any one of claims 1, 2 or 4, wherein said access means comprises a "U" shaped tab die cut (44) in said top wall.

6. A package according to claim 5, wherein said closure flap is secured to said top wall by said peripheral seal and at least one substantially transverse seal (48), said transverse seal securing said closure flap to said tab.

7. A package according to any one of the preceding claims, wherein said retainer includes at least one suture-needle assembly (20) positioned within the package such that the needle (22) is accessible through said top wall.

8. A package according to claim 8, wherein said suture-needle assembly is packed in a fluid medium.

9. A method for packaging a surgical suture retainer in conditioning fluid, comprising the steps of:

forming a bottom wall of substantially moisture impervious material;

forming a top wall of substantially moisture impervious material having the same dimensions as said bottom wall;

forming an access opening in said top wall;

forming a closure flap of substantially moisture impervious material to overlie less than the entirety of said top wall;

securing said closure flap to said top wall with a peelable seal about a periphery of said flap to enclose said access opening, said seal including a portion which extends across the package;

positioning said retainer on said bottom wall;

securing said top wall having said closure flap thereon to said bottom wall with a non-peelable heat seal about a periphery of said top and bottom walls to enclose said retainer therein.

10. A method according to claim 9, wherein said step of forming an access opening in said top wall comprises forming a U-shaped tab in said top wall.

11. A method according to claim 10, further comprising the step of securing said closure flap to said tab.

12. A method according to any one of claims 9 to 11, wherein said top wall is secured to said bottom wall by a peripheral heat weld seal.

13. A method according to any one of claims 9 to 12, wherein said closure flap is secured to said top wall by a peripheral peelable heat seal.

14. A method according to any one of claims 9 to 13, wherein said retainer comprises a plurality of suture-needle assemblies, positioned within the package such that needles of said assemblies are beneath said access opening in said top wall.

Patentansprüche

1. Verpackung (10) für einen chirurgische Nahtmaterialhalter (18) in Konditionierfluid, umfassend:

eine Wand (14) aus einem im wesentlichen feuchtigkeitsundurchlässigem Material, das einen Boden der Verpackung bildet,

eine Wand (12) aus einem im wesentlichen feuchtigkeitsundurchlässigem Material, das eine Oberseite der Verpackung bildet, wobei die oberseitige Wand im wesentlichen dieselben Abmessungen wie die unterseitige Wand (12) besitzt und in einer überlappenden Beziehung auf der unterseitigen Wand angeordnet ist, um dazwischen eine Tasche zur Aufnahme des Halters zu bilden, wobei die oberseitige Wand an der unterseitigen Wand durch eine im wesentlichen feuchtigkeitsundurchlässige Umfangsabdichtung (30) befestigt ist, wobei die Umfangsabdichtung (30) zwischen der oberseitigen und der unterseitigen Wand nicht abziehbar ist;

eine Einrichtung (24, 42), um Zutritt zu dem Halter durch die oberseitige Wand zu besitzen, und

eine Schließklappe (16) aus einem im wesent-

lichen feuchtigkeitsundurchlässigem Material, das zumindest über einem Bereich der oberseitigen Wand liegt und die Zutrittseinrichtung einschließt, wobei die Schließklappe an der oberseitigen Wand durch eine im wesentlichen feuchtigkeitsundurchlässige, abziehbare, Umfangsabdichtung (32) befestigt ist, wobei

die Schließklappe (16) über weniger als der Gesamtheit der oberseitigen Wand (14) liegt und die abziehbare Abdichtung (32), welche die Schließklappe an der oberseitigen Wand befestigt, einen Bereich aufweist, der sich über die Verpackung hinweg erstreckt.

2. Verpackung gemäß Anspruch 1, wobei die Schließklappe eine Greiflasche (34) umfaßt, um das Entfernen der Schließklappe von der oberseitigen Wand zu erleichtern.

3. Verpackung gemäß einem der Ansprüche 1 oder 2, wobei die Zutrittseinrichtung einen Ausschnittsbereich (24) in der oberseitigen Wand umfaßt.

4. Verpackung gemäß einem der vorhergehenden Ansprüche, wobei die im wesentlichen feuchtigkeitsundurchlässige Umfangsabdichtung zwischen der unterseitigen Wand und der oberseitigen Wand eine Wärmeversiegelung (30) ist und

die Zutrittseinrichtung einen Bereich des Halters (18) freilegt, wobei die Zutrittseinrichtung von der Schließklappe eingeschlossen und durch diese abgedichtet ist.

5. Verpackung gemäß einem der Ansprüche 1, 2 oder 4, wobei die Zutrittseinrichtung eine U-förmige, ausgestanzte Lasche (44) in der oberseitigen Wand umfaßt.

6. Verpackung gemäß Anspruch 5, wobei die Schließklappe an der oberseitigen Wand durch die Umfangsversiegelung und durch eine im wesentlichen quer verlaufende Versiegelung (48) befestigt ist, wobei die quer verlaufende Versiegelung die Schließklappe an der Lasche befestigt.

7. Verpackung gemäß einem der vorhergehenden Ansprüche, wobei der Halter zumindest einen Nahtmaterial-Nadelaufbau (20) umfaßt, der innerhalb der Verpackung so angeordnet ist, daß die Nadel (22) durch die oberseitige Wand zugänglich ist.

8. Verpackung gemäß Anspruch 8, wobei der Nahtmaterial-Nadelaufbau in einem Fluidmedium verpackt ist.

9. Verfahren zum Verpacken eines chirurgischen Nahtmaterialhalters in einem Konditionierfluid, umfassend die Schritte:

Formen einer unterseitigen Wand aus einem im wesentlichen feuchtigkeitsundurchlässigen Material;

Formen einer oberseitigen Wand aus einem im wesentlichen feuchtigkeitsundurchlässigen Material mit denselben Abmessungen wie die unterseitige Wand;

Formen einer Zutrittsöffnung in der oberseitigen Wand;

Formen einer Schließklappe aus einem im wesentlichen feuchtigkeitsundurchlässigen Material, das weniger als über der Gesamtheit der oberseitigen Wand liegt;

Befestigen der Schließklappe an der oberseitigen Wand mit einer abziehbaren Abdichtung um einen Rand der Klappe, um die Zutrittsöffnung zu umschließen, wobei die Abdichtung einen Bereich aufweist, der sich über die Verpackung erstreckt;

Positionieren des Halters auf der unterseitigen Wand;

Befestigen der oberseitigen Wand mit der Schließklappe darauf an der unterseitigen Wand mit einer nicht abziehbaren Wärmeversiegelung um einen Rand der oberseitigen und unterseitigen Wände, um den Kalter darin einzuschließen.

10. Verfahren gemäß Anspruch 9, wobei der Schritt des Bildens einer Zutrittsöffnung in der oberseitigen Wand das Formen einer U-förmigen Lasche in der oberseitigen Wand umfaßt.

11. Verfahren gemäß Anspruch 10, weiter umfassend den Schritt des Befestigens der Schließklappe an der Lasche.

12. Verfahren gemäß einem der Ansprüche 9 bis 11, wobei die oberseitige Wand an der unterseitigen Wand durch eine am Umfang verlaufende Wärmeschweißversiegelung befestigt ist.

13. Verfahren gemäß einem der Ansprüche 9 bis 12, wobei die Schließklappe an der oberseitigen Wand durch eine abziehbare Wärmeversiegelung am Rand befestigt ist.

14. Verfahren gemäß einem der Ansprüche 9 bis 13,

wobei der Halter eine Mehrzahl von Nahtmaterial-Nadelaufbauten umfaßt, die innerhalb der Verpakkung so angeordnet sind, daß die Nadeln der Aufbauten unter der Zutrittsöffnung in der oberseitigen Wand sind.

Revendications

1. Emballage (10) pour un élément de retenue de suture chirurgical (18) dans un fluide de conditionnement comprenant :

   une paroi (12) en un matériau sensiblement étanche à l'humidité formant un fond dudit emballage,
   une paroi (14) en un matériau sensiblement étanche à l'humidité formant un dessus dudit emballage, ladite paroi supérieure ayant sensiblement les mêmes dimensions que ladite paroi inférieure et étant positionnée suivant une relation de recouvrement sur ladite paroi inférieure pour former une poche entre celles-ci pour recevoir ledit élément de retenue, ladite paroi supérieure étant fixée à ladite paroi inférieure par un joint périphérique sensiblement étanche à l'humidité (30), le joint périphérique (30) entre les parois inférieure et supérieure étant non pelable ;
   des moyens (24, 42) pour accéder audit élément de retenue à travers ladite paroi supérieure et
   un volet de fermeture (16) en un matériau sensiblement étanche à l'humidité recouvrant au moins une partie de ladite paroi supérieure et enfermant ledit moyen d'accès, ledit volet de fermeture étant fixé à ladite paroi supérieure par un joint périphérique pelable (32) sensiblement étanche à l'humidité,
   où le volet de fermeture (16) recouvre moins que la totalité de la paroi supérieure (14) et le joint pelable (32) qui fixe le volet de fermeture à la paroi supérieure comporte une partie qui s'étend à travers l'emballage.

2. Emballage selon la revendication 1, où ledit volet de fermeture comporte une patte de préhension (34) pour faciliter le retrait dudit volet de ladite paroi supérieure.

3. Emballage selon l'une des revendications 1 ou 2, où ledit moyen d'accès comprend une région découpée (24) dans ladite paroi supérieure.

4. Emballage selon l'une des revendications précédentes, où le joint périphérique étanche à l'humidité entre lesdites parois inférieure et supérieure est un thermosoudage (30) et

   ledit moyen d'accès expose une partie dudit élément de retenue (18), ledit moyen d'accès étant enfermé et rendu étanche par ledit volet de fermeture.

5. Emballage selon l'une des revendications 1, 2 ou 4, où ledit moyen d'accès comprend une découpure en forme de "U" (44) dans ladite paroi supérieure.

6. Emballage selon la revendication 5, où ledit volet de fermeture est fixé à ladite paroi supérieure par ledit scellement périphérique et au moins un scellement sensiblement transversal (48), ledit scellement transversal fixant ledit volet de fermeture à ladite patte.

7. Emballage selon l'une des revendications précédentes, où l'élément de retenue comporte au moins un ensemble de fil de suture et d'aiguille (20) positionné dans l'emballage de façon que l'aiguille (22) soit accessible à travers ladite paroi supérieure.

8. Emballage selon la revendication 8, où ledit ensemble de fil de suture et d'aiguille est emballé dans un milieu de fluide.

9. Procédé pour emballer un élément de retenue de suture chirurgical dans un fluide de conditionnement, comprenant les étapes consistant à :

   former une paroi inférieure en un matériau sensiblement étanche à l'humidité ;
   former une paroi supérieure en un matériau sensiblement étanche à l'humidité ayant les mêmes dimensions que ladite paroi inférieure ;
   réaliser une ouverture d'accès dans ladite paroi supérieure ;
   former un volet de fermeture en un matériau sensiblement étanche à l'humidité pour recouvrir moins que la totalité de ladite paroi supérieure ;
   fixer ledit volet de fermeture à ladite paroi supérieure avec un scellement pelable autour d'une périphérie dudit volet pour enfermer ladite ouverte d'accès, ledit scellement incluant une portion qui s'étend à travers l'emballage ;
   positionner ledit élément de retenue sur ladite paroi inférieure ;
   fixer ladite paroi supérieure sur laquelle se trouve ledit volet de fermeture à ladite paroi inférieure avec un thermosoudage non pelable autour d'une périphérie desdites parois supérieure et inférieure pour enfermer ledit élément de retenue dans celles-ci.

10. Procédé selon la revendication 9, où ladite étape consistant à former une ouverture d'accès dans ladite paroi supérieure comprend la formation d'une

patte configurée en U dans ladite paroi supérieure.

11. Procédé selon la revendication 10, comprenant en outre l'étape consistant à fixer ledit volet de fermeture à ladite patte.

12. Procédé selon l'une des revendications 9 à 11, où ladite paroi supérieure est fixée à ladite paroi inférieure par un thermosoudage périphérique.

13. Procédé selon l'une des revendications 9 à 12, où ledit volet de fermeture est fixé à ladite paroi supérieure par un thermosoudage périphérique pelable.

14. Procédé selon l'une des revendications 9 à 13, où ledit élément de retenue comprend une pluralité d'ensembles de fil de suture et d'aiguille, positionnés dans l'emballage de façon que les aiguilles desdits ensembles se situent en dessous de ladite ouverture d'accès dans ladite paroi supérieure.

FIG. 1

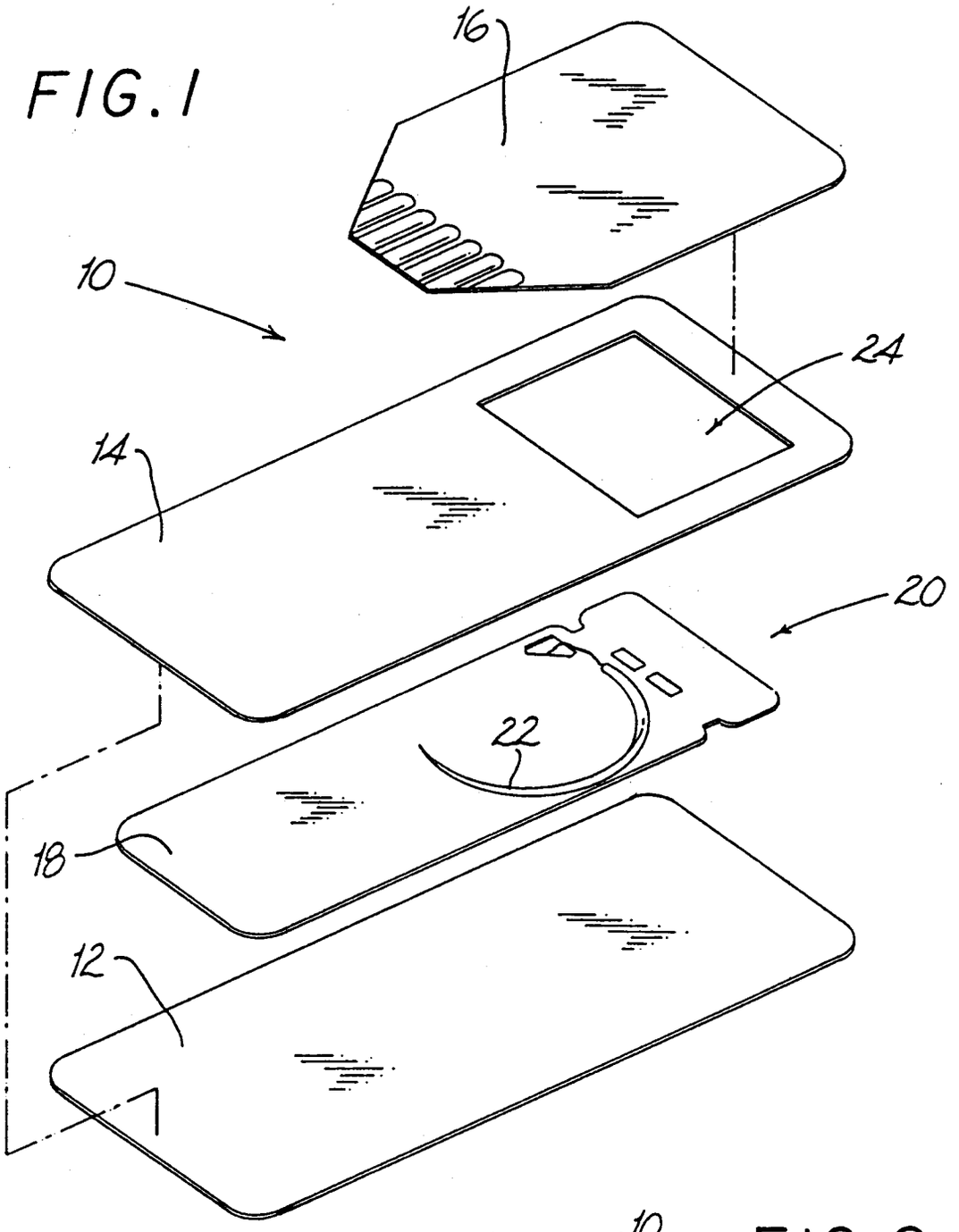

FIG. 2

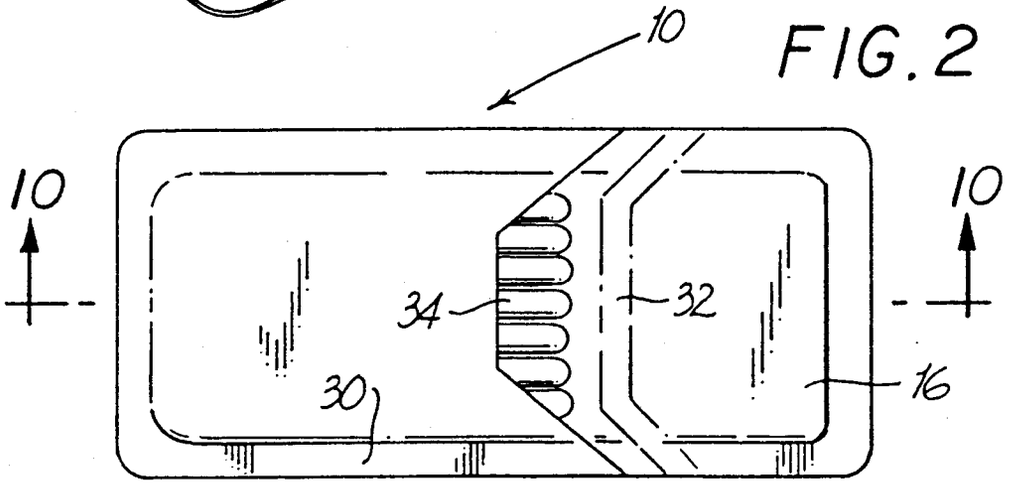

FIG. 3

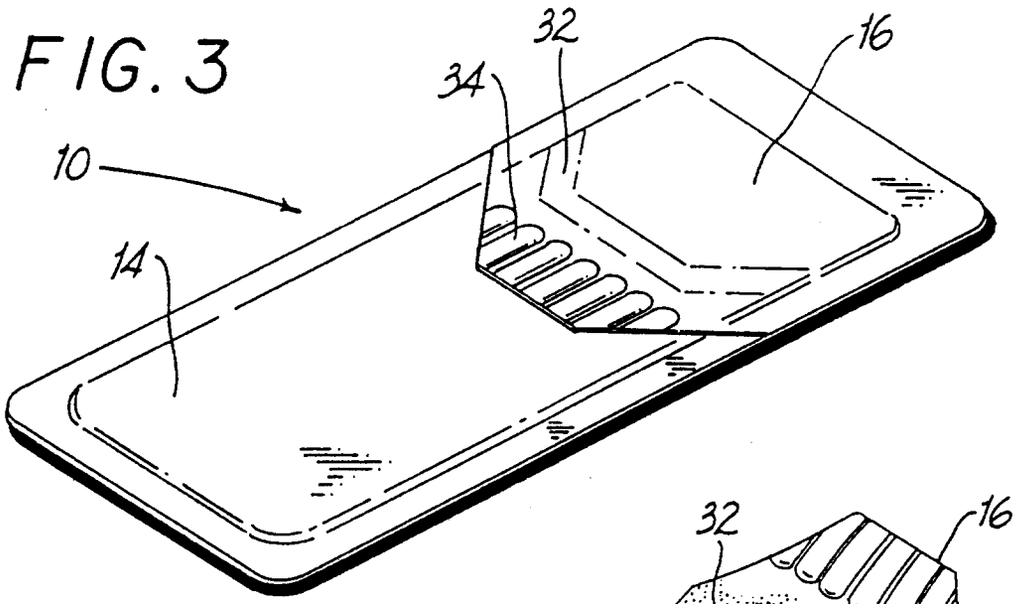

FIG. 4

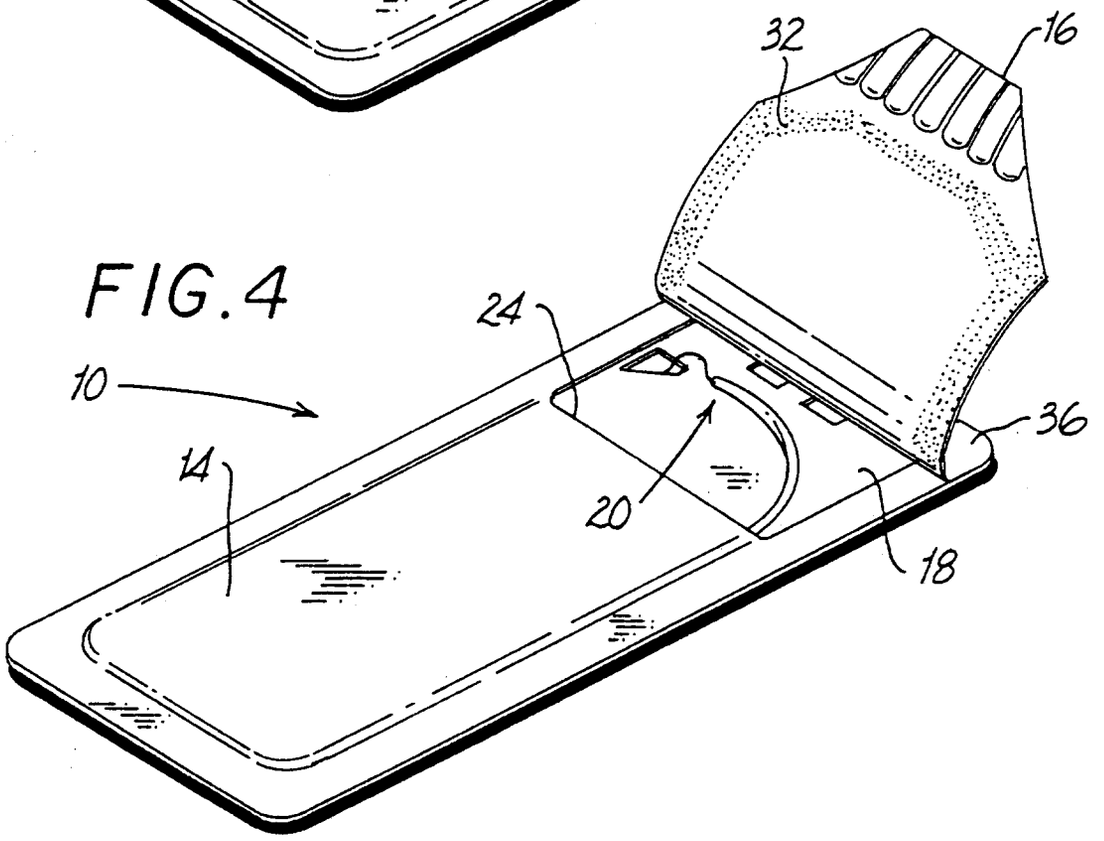

FIG. 10

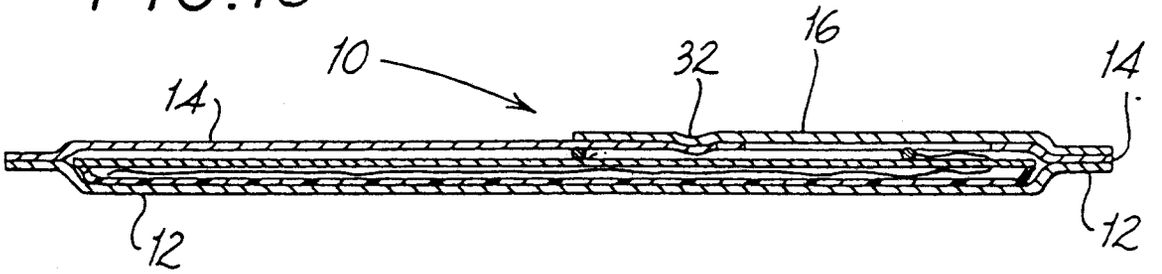

FIG.5

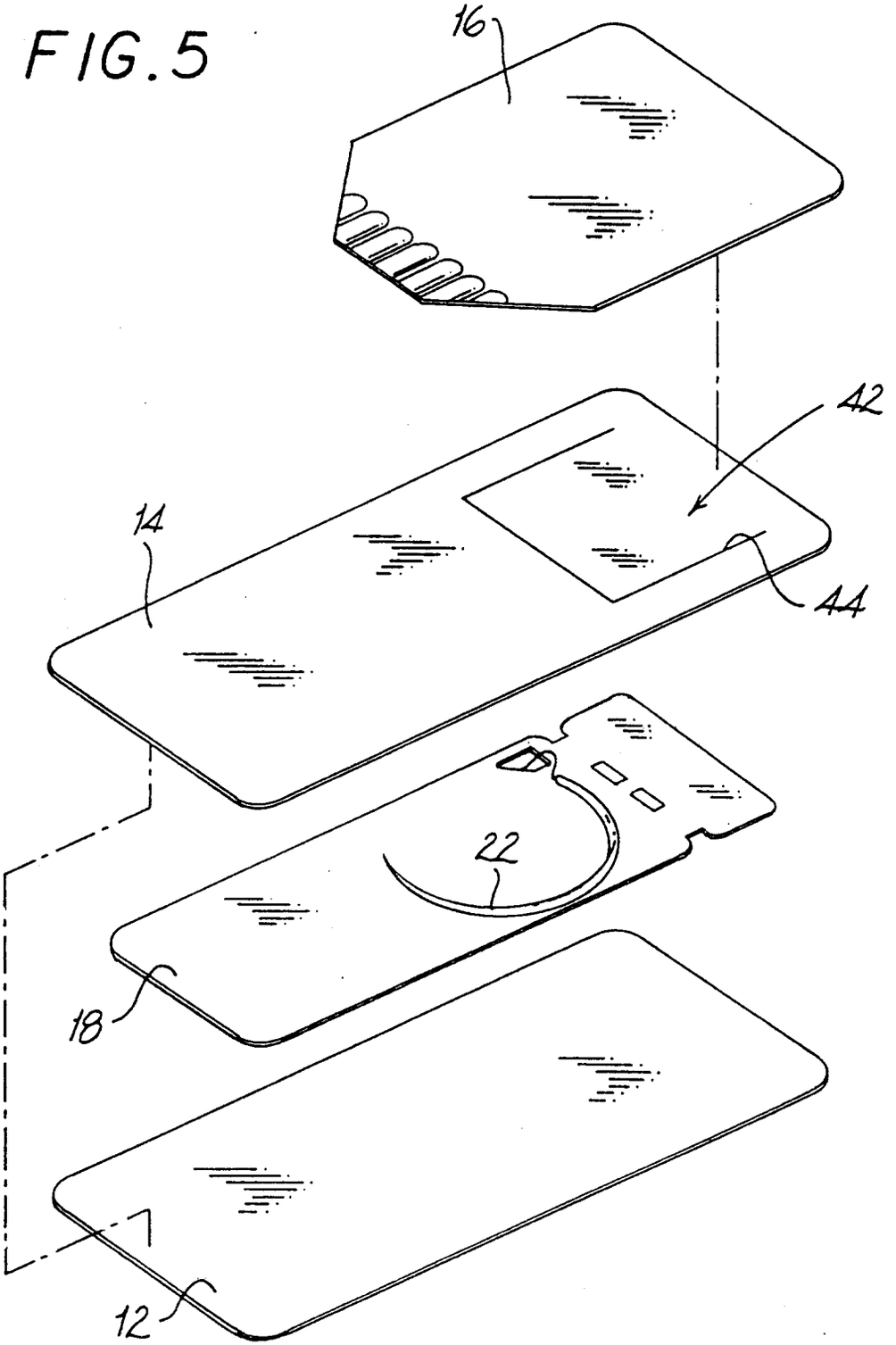

FIG. 6

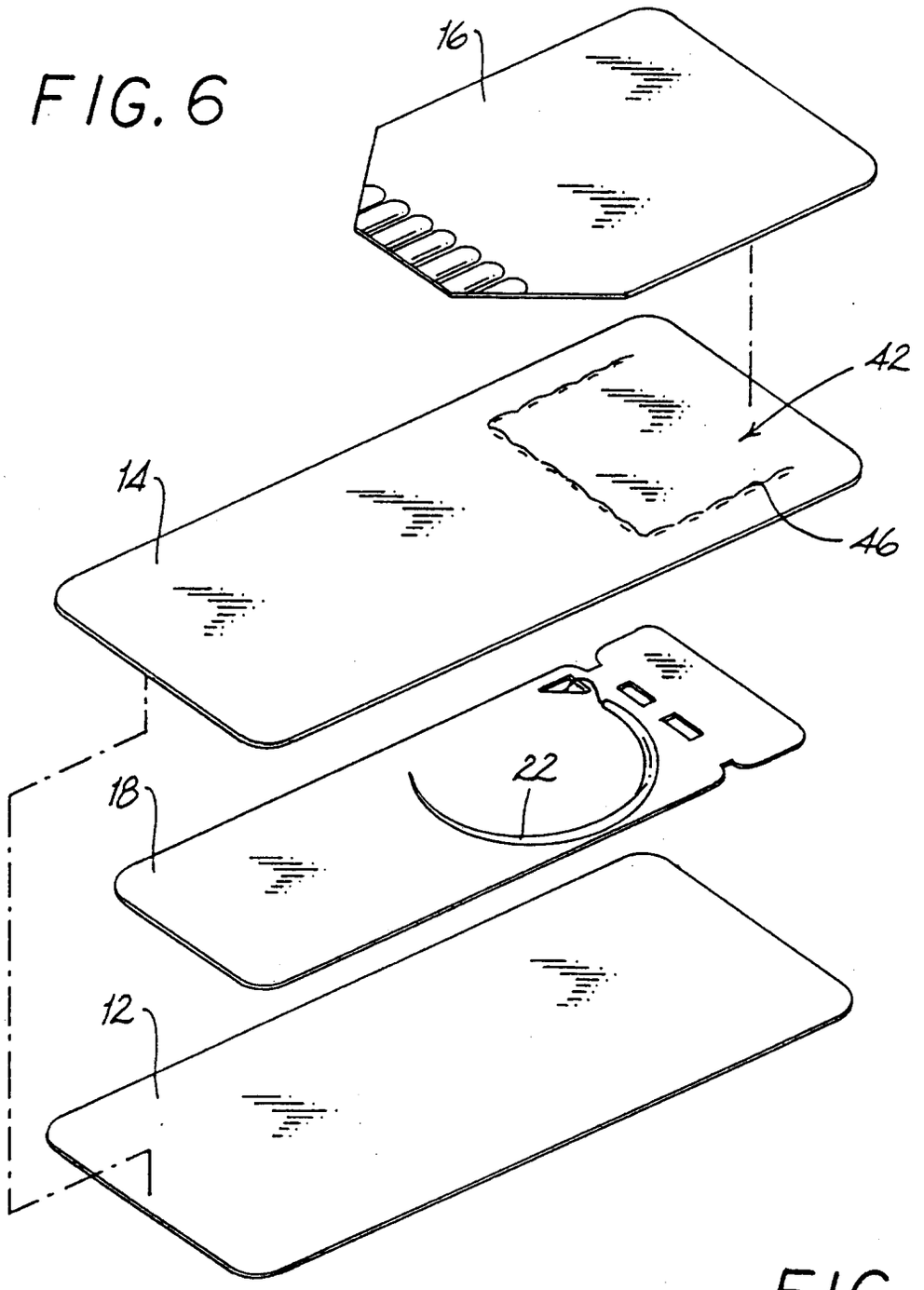

FIG. 7

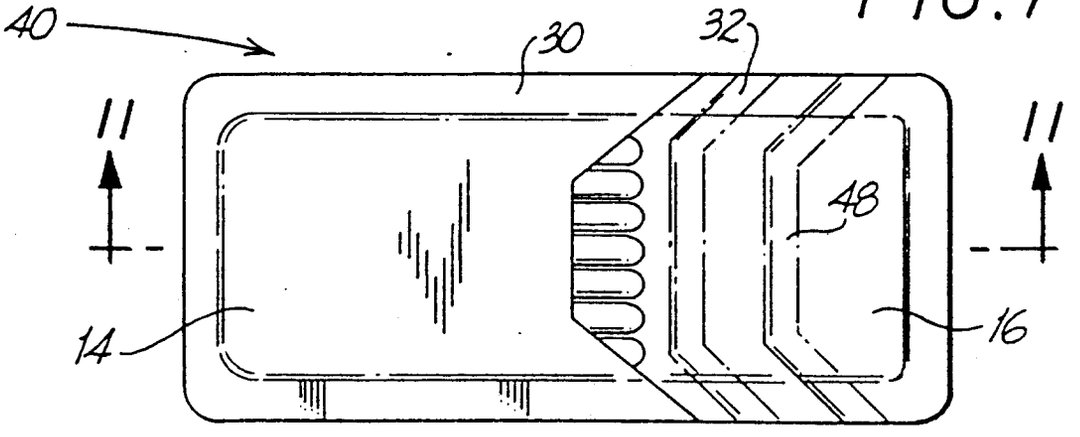

FIG.8

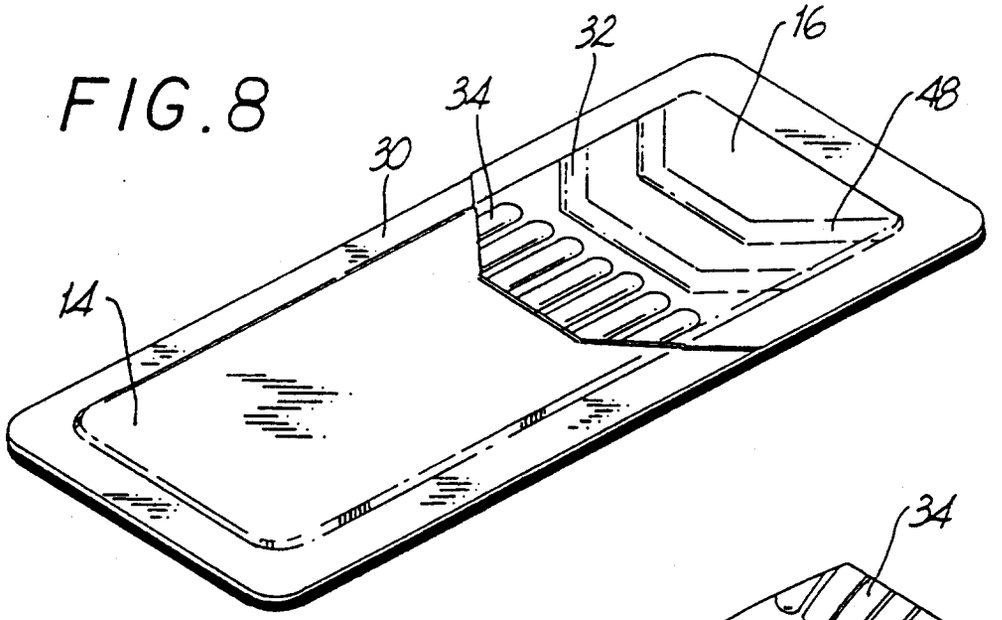

FIG.9

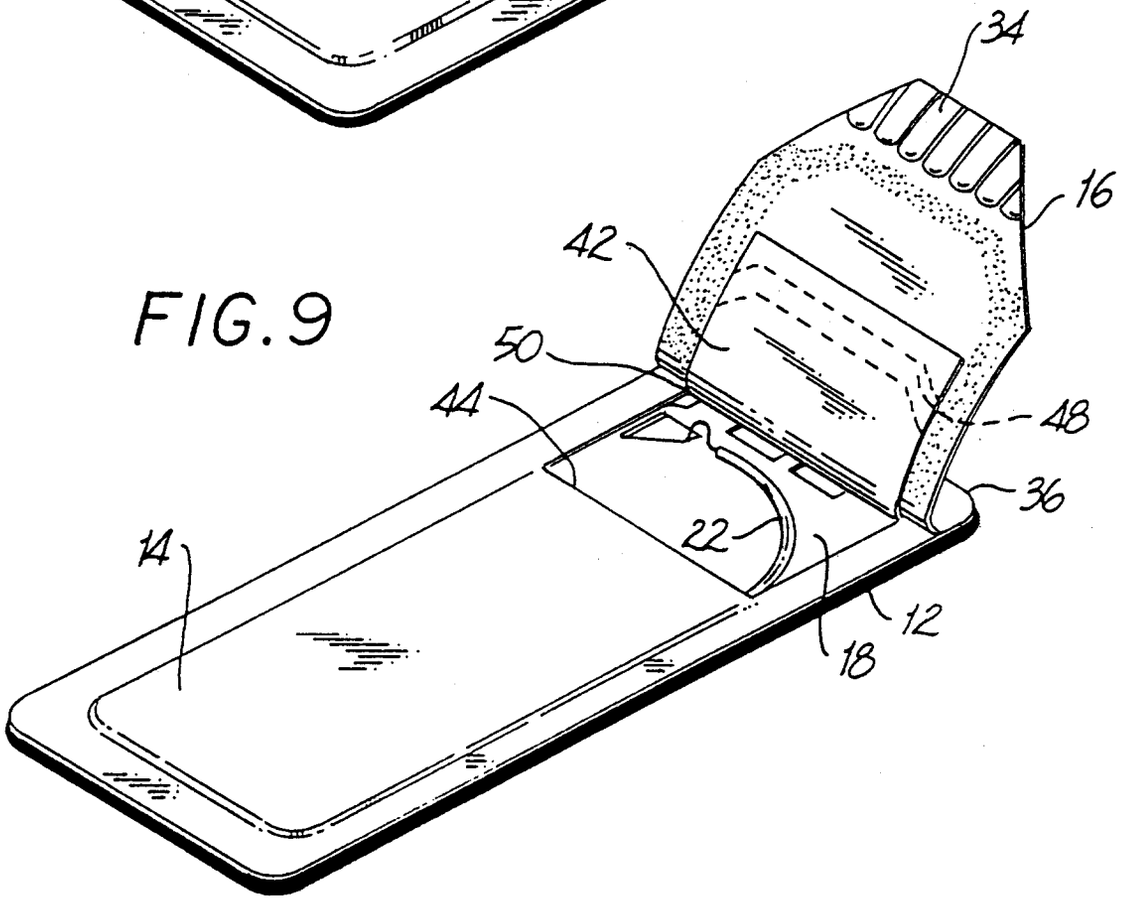

FIG.11